

### **REMARKS/ARGUMENTS**

Claims 1, 9, 10 and 11 have been amended. Claim 12 has been canceled. Claims 1, 2, 4-11, 13 and 14 are pending. No new matter has been added. Reconsideration of the application is respectfully requested in view of the amendments and the following remarks.

#### **Drawings**

The drawings were objected to, in particular, that the end faces being convex must be shown in the drawing or the features must be canceled from the claims.

First, applicants assert that the end face 2<sub>1</sub> in FIG. 2 does show a convex shape in a plane through the center of the convex shape. As can be seen in FIG. 2, there is a parallel line above the leader line pointing to end face 2<sub>1</sub>, this parallel line being upper portion of the convex shape and the leader line pointing to the lower portion (i.e. trough) of the convex shape. FIG. 2 also shows the transverse surface 14 extending below the parallel line into the convex shape.

Second, it is Applicants understanding that drawings are only required "where necessary for the understanding of the subject matter sought to be patented." (35 U.S.C. §113). If it is determined that the convex shape is not disclosed in FIG. 2, Applicant asserts that a person skilled in the art would understand the term "convex", as described in the specification, and how it applies to the ball-and-socket joint 7 and the end face 2<sub>1</sub> of the device. See particularly, paragraph [0022] "Advantageously, the transverse face 14 of the ball-and-socket joint 7 and/or the end face 2<sub>1</sub> of the bone anchoring element 2 have a convex shape in order to allow such an orientation with limited bulkiness."

Accordingly, for at least the reasons stated above, Applicant respectfully requests withdrawal of this objection to the drawings.

#### **Double Patenting**

The Office Action alleges that should claim 1 be found allowable, claim 12 will be objected to as being a substantial duplicate thereof.

To expedite prosecution, Applicant has canceled claim 12, rendering this potential objection moot.

**Rejections Under 35 U.S.C. §112**

Claim 9 is rejected as being indefinite, in particular, that there is insufficient antecedent basis for the limitation “the receiving head”. The Examiner interpreted “the receiving head” limitation as the head of the bone anchoring element, which is correct.

Claim 9 has been amended to agree with the Examiners interpretation of the claim, changing “the receiving head” to “the head”. Applicant respectfully requests withdrawal of this rejection.

**Rejections Under 35 U.S.C. §103**

A. Claims 1, 2, 4-8 and 10-14 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bernhardt (U.S. Patent 5,591,166) in view of Bjors (U.S. Patent 4,055,385). Applicants respectfully traverse this rejection.

The Office Action alleges that Bernhardt discloses the elements of claim 1 except Bernhardt does not disclose a rotational linkage means. The Office Action further alleges that Bjors discloses

“a rotational linkage means (see Figure 4) longitudinally positioned on the end faces of the elements ... comprising a male geometrical form having a non-circular cross-section (the trapezoidal shaped projection extending from surface 28) tending from the ball and a female geometrical form having a non-circular cross-section (the receptacle extending from surface 29), wherein both end faces include convex portions and flat portions in order to limit movement between the elements relative to one another”

and that it would have been obvious to one having ordinary skill in the art to combine the device of Bernhardt with the rotational linkage means of Bjors in order to limit the movement between the bone anchor element and the threaded shaft.

It appears that there may be a misunderstanding on what is disclosed in Bjors and what the rotational linkage means actually does. The movement described in Bjors is angular rotational movement between the components and Bjors discloses limiting this angular movement. For example, FIG. 1 shows the “rotation” between the sphere 16 in the socket 13 as angle  $\alpha$  and angle  $\beta$ . The specification states:

“The 15° rotation, previously alluded to herein, is shown as angle  $\alpha$  in FIG. 1. 75° rotation, previously alluded to, is the complementary angle  $\beta$ , also shown in FIG. 1. The truncated portion 19 abuts the surface of the workpiece. Where necessary, the ball 16 is rotated within the socket 15° to accomplish this.” (Bjors, col. 3, lines 42-47).

In regards to FIG. 4, Bjors states:

“In FIG. 4 yet another embodiment of the invention is shown wherein the tool clamp 11 has a screw member 12, having threads 14 and socket 13 for receiving a truncated sphere 16. A portion of the other surface of the truncated sphere within the socket 13 has a circumferential cavity therein 28. A corresponding portion of the socket has a circumferential protrusion 29 juxtaposed to the cavity and inserted within the cavity. There is sufficient clearance within the cavity 28 to enable the sphere 16 to rotate within the socket, but to be limited in that rotation to a desired amount, such as approximately 15° in any direction.” (Bjors, col. 3, lines 10-21)

It is clear from the figures and specification of Bjors that the limiting of movement between the components is limiting angular rotation.

In contrast, the rotational linkage means disclosed in the present application includes axial rotation, and how the components can be locked in axial rotation while allowing angular rotation (termed “orientation” in the present application). See [0018], “the bone anchoring element 2 and the threaded shaft 4 are directly linked in rotation while maintaining multiple orientation for the threaded shaft 4 relatively to the bone anchoring element 2” and [0020], “a rotational force exerted along the axis of the bone anchoring element 2 or of the threaded shaft 4

leads to rotational locking between the bone anchoring element 2 and the threaded shaft 4, regardless of the relative orientation between these two parts.”

To further distinguish the present claims from the prior art, Applicant has amended rotational linkage means of claims 1, 10 and 11 to clarify that “rotational force exerted along an axis of the bone anchoring element or of the threaded shaft leads to rotational locking between the bone anchoring element and the threaded shaft, regardless of the multiple orientation of the threaded shaft relative to the bone anchoring element”.

Bernhardt and Bjors, either separately or in combination, fail to disclose a “rotational force exerted along an axis of the bone anchoring element or of the threaded shaft leads to rotational locking between the bone anchoring element and the threaded shaft”.

Accordingly, for at least the reasons discussed above, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-8 10, 11, 13 and 14.

**B.** Claims 9 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bernhardt (U.S. Patent 5,591,166) in view of Bjors (U.S. Patent 4,055,385) further in view of Mullane (U.S. Patent 5,628,740). Applicants respectfully traverse this rejection.

Claim 9 ultimately depends on claim 1, which the Applicant has shown above to be allowable over the combination of Bernhardt in view of Bjors. Applicant submits that Mullane does not add anything that would remedy the aforementioned deficiency in the combination of Bernhardt in view of Bjors.

Accordingly, for at least the reasons discussed above, Applicant respectfully requests withdrawal of the rejection of claim 9.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees associated with this paper, or credit any overpayment, to Deposit Account No. 50-4978.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 760-494-6835.

Respectfully submitted,

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